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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
PELLEGRINO, BRIAN E	
ART UNIT	PAPER NUMBER
3738	

MAIL DATE	DELIVERY MODE
11/24/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/623,908	KAWULA, PAUL JOHN	
	Examiner	Art Unit	
	Brian E. Pellegrino	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 July 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *6-29 and 47-52* is/are pending in the application.

4a) Of the above claim(s) *9-21 and 24-26* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *6-8,22,23,27-29 and 47-52* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *7/7/08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

The amendment filed on 7/31/08 is sufficient to overcome the 112 2nd paragraph rejection.

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 6,22,23,49,52 are rejected under 35 U.S.C. 102(b) as being anticipated by Cremascoli (4813959). Fig. 1 shows a medical device (1) for implanting in a patient. It can be seen that the device has an attachment *region* within the surface in the form of an indentation in the outer surface and has a porous ceramic region (6) disposed therein and a second less porous ceramic region (5). The second porous region (5) is positioned in between the first porous region (6) and the attachment region of the device (3) such that the first porous region and attachment region are located on opposite sides of the second porous region. Cremascoli discloses the material is ceramic, col. 2, lines 5-8,19. The device is made of metal, such as stainless steel (col. 1, line 63, col. 2, lines 34,35) and comprises the ceramic components. Please note claims 49,52 include product by process limitations and are not governed by the process how it is achieved. Thus, the indentations of the attachment region are fully capable of being machined or have material removed.

Claims 6,22,23,47,49-52 are rejected under 35 U.S.C. 102(b) as being anticipated by Pope et al. (6290726). Figs. 3B, 3N,3O show a medical device having a body **383,344,347** with an outer surface and attachment region with indentations **384,345,349** respectively in the surface. It can also be seen there is a ceramic component **382,343,346** disposed in the indentations respectively. Pope discloses the material for the body of the device can be metal, such as steel, col. 11, lines 17-27. Figs. 4B,4BB illustrate that upon fusing a substrate with a coating there are two regions established, the outer porous region, and the less porous region or transition region where the bond or fusing has occurred. Thus, the less porous region is between the more porous region and the attachment region. Pope discloses carbides can be fused onto the substrate, col. 30, lines 28-37. Pope additionally discloses the materials for the ceramic component can be quartz, col. 11, lines 16,17,35,36. Pope also discloses an oxide layer can be placed between the substrate, col. 36, lines 56-59. Pope additionally discloses the indentations can have material removed or machined, col. 44, lines 43-47.

Claims 6-8,22,23,27,29,47-49,52 are rejected under 35 U.S.C. 102(e) as being anticipated by Gayer et al. (6461385). Gayer et al. disclose a medical device formed of wires, col. 5, lines 34,40. Gayer also discloses the wires are made of metal such as titanium, stainless steel or gold, col. 7, lines 49,50. Fig. 1 shows the implant body surface **104** having attachment regions in the form of indentations **106.** Fig. 5 shows the process of coating the device **400** where the surface is coated with an oxide layer **402**. Regarding claim 48, the oxide layer is of the material that the body is comprised, col. 9, lines 54-56. With respect to claim 49, Gayer discloses removing some of the material to

form attachment regions, col. 7, lines 33-35. Gayer then discloses to coat the oxide layer with a ceramic **404** as seen in Fig. 6, col. 10, line 20. The Examiner is not giving any special definition to "fused" it is interpreted to just mean attached and Gayer discloses the less porous ceramic component (404) is attached to the oxide layer (402), see col. 10, lines 5-11. Then the ceramic layer has a porous layer or side placed thereon **406** as seen in Fig. 7. Gayer discloses the porous side has ceramic disposed therein, col. 10, lines 42,49. With respect to claims 7,8,29, Gayer discloses the porous region has a drug, such as an anti-inflammatory, col. 5, lines 49,51,55,56. Please note claims 49,52 include product by process limitations and are not governed by the process how it is achieved. Thus, the indentations of the attachment region are fully capable of being machined or have material removed.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 7,8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cremascoli '959 in view of Alt (60999561). Cremascoli is explained supra. However, Cremascoli fails to disclose the use of a drug with ceramic implants. Alt teaches that drugs are commonly used with ceramic coated implants to make the device more biocompatible by using an anti-inflammatory, col. 10, lines 42-61. It would have been obvious to one of ordinary skill in the art to incorporate an anti-inflammatory drug in the

porous ceramic as taught by Alt with the medical device of Cremascoli such that it reduces inflammation at the site of implantation to permit the device to be used.

Claim 28 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gayer et al. '385 in view of Ding et al. (2002/91433) or Yan (6240616). Gayer et al. is explained supra. However, Gayer et al. fail to disclose the medical implant can be a stent. It is well known in the art that wires are used to form stents and also include coatings as disclosed by Gayer to be used in the vascular system. Both Ding et al. and Yan teach stents are made from metal wires and that the stent is coated with a drug. It would have been obvious to one of ordinary skill in the art to use the coated drug wires of Gayer et al. and form a stent as taught by Ding or Yan since the therapeutic wires are biocompatible and capable of supporting a vessel by forming a stent disclosed in Ding or Yan.

Response to Arguments

Applicant's arguments filed 7/31/08 have been fully considered but they are not persuasive. Applicant argues that the ceramic component of the Cremascoli device forming a less porous region (5) is not located between the porous ceramic region (6) and the attachment region. However, Applicant is reminded that claim 6 recites the attachment region is within the surface of the device of which is clearly evident that an "attachment region" of the device of Cremascoli having body (3) clearly has within its surface attachment region. The Examiner is not giving any special definition to the

terms “attachment region” when the claim does not set for any particular structure. Cremascoli can be said to meet the claim language.

Applicant argues that the ceramic component comprising the less porous region is not fused in the indentations. However, the Examiner as mentioned above, the Examiner is not giving any special definition to the term fuse to be limited to some process. It just means to be attached and clearly the less porous region of ceramic (404) of the Gayer apparatus is “fused” to the indentations via the oxide layer. Applicant also argues that there is no second porosity ceramic disclosed by Gayer. However, the Examiner reminds Applicant that the claims use the transitional phrase comprising and further a "ceramic component" which provides no special meaning or structure. The Examiner interprets this such that so long as ceramic material is present, it meets the claim. Applicant appeared to ignore where the Examiner clearly pointed out that a ceramic material is present in this second porous region and refers Applicant again to col. 10, lines 42,49. Hydroxyapatite is clearly ceramic material. Arguments are not persuasive.

Applicant failed to indicate that the 103 rejections were not obvious in that the teaching references used in the rejections lacked the claimed limitations. Thus, since the anticipation rejections have not been overcome the teaching references used in combination were proper and are the 103 rejections are maintained.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian E. Pellegrino whose telephone number is 571-272-4756. The examiner can normally be reached on M- F (7am-5:30pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

TC 3700
/Brian E Pellegrino/
Primary Examiner, Art Unit 3738